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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/954,512	09/12/2001	Jerry Pelletier	514012000300	8460

7590 05/07/2003

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EXAMINER
HASHEMI, SHAR S

ART UNIT	PAPER NUMBER
1637	13

DATE MAILED: 05/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/954,512	PELLETIER, JERRY	
	Examiner	Art Unit	
	Shar Hashemi	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 12-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 12-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. The applicant's response to the Office Action has been entered. The applicant's response was received on 03 Feb 03 and has been entered as paper no. 12. The claims pending in this application are **Claims 1-9 and 12-21.** Rejections and/or objections not reiterated from the previous office action are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

Response to Arguments

2. According to the applicant, 1) Allen does not teach that NCp7 or nucleocapsid protein increases the processivity of RT, 2) "the "structures are not internal structures to the nucleic acid to be amplified as in the present invention, but ligands which are aimed at inhibiting and not increasing the processivity of the reverse transcriptase, 3) there is no motivation to combine the temperature cycling and reverse transcriptase cycling method of Legerski and the HIV RNA binding proteins of Allen because "Allen aims at inhibiting nucleocapsid function and not at increasing the processing of RT. Applicant's arguments have been fully considered but they are not persuasive.

Sequence Rules

3. This application now complies with the sequence rules and the sequences have been entered by the Scientific and Technical Information Center.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 13 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) The unlabelled nucleotide sequences recited in claims 13 and 16 are confusing. It is unclear as to which SEQ ID NO "identifier" corresponds to these nucleotide sequences. Furthermore, it is unclear as to whether these unlabelled nucleotide sequences correspond to SEQ ID NO "identifiers" or a portion of a larger sequence. Amending the claims to label each nucleotide sequence with a SEQ ID NO "identifier" wou8ld obviate the rejection.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-9, 12, 14-15, 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Legerski (US 6, 406, 891 B1 June 18, 2002) in view of Allen et al (US 5, 654, 151 August 5, 1997).

Legerski in US 6, 406, 891 B1 teaches a method for the synthesis of full length cDNAs utilizing a highly processive RNA-dependent DNA polymerase (see whole document especially col. 2, lines 32-56). He also teaches the use of RNA-dependent RNA polymerases (col. 21, lines 30-36), RNA-dependent DNA polymerase and DNA-dependent DNA polymerases (col. 9, lines 15-36) in the above method. He teaches MMLV and AMV reverse transcriptases (col. 7, lines 54-67). He teaches reverse transcribing RNA in the presence of processivity inhibiting structure (col. 2, lines 56-59). He teaches a polymerization composition having template nucleic acid, polymerase, and buffer (col. 13, lines 1-30).

Legerski in US 6, 406, 891 B1 does not teach binding proteins. He does not teach retroviral nucleocapsid RNA binding proteins. He does not teach NCp7. He does not teach reverse transcribing RNA in the presence of both inhibiting structures and increasing agents. He does not teach comparing the length of the polymerized products is measurably higher in the presence of the candidate agent than in the absence thereof. He does not teach a polymerization composition having a general RNA binding protein.

Allen et al in US 5,654,151 teach retroviral nucleocapsid RNA binding proteins increase the processivity of reverse transcriptase (col. 1, lines 45-67). They teach NCp7 (col. 20, lines 6-10). They teach reverse transcribing RNA where both inhibiting structures and increasing agents are present (col. 4, lines 33-45). They teach comparing the length of the polymerized products is measurably higher in the presence of the candidate agent than in the absence thereof

(col. 5, lines 15-66). They teach a polymerization composition having a general RNA binding protein (col. 8, lines 25-67).

One of ordinary skill at the time the invention was made would have been motivated to apply Allen et al's nucleocapsid protein to Legerski's US 6, 406, 891 B1 method for the synthesis of full length cDNAs utilizing highly processive RNA-dependent DNA polymerases in order to enhance processivity by over two orders of magnitude (col. 1, lines 50-65) because nucleocapsid protein is characterized to 1) increase processivity of DNA synthesis by reducing RT pausing regions of stable secondary structures in the template RNA, 2) contribute to the synthesis of full-length viral cDNA, 3) increase the efficiency with which RT was able to reverse transcribe, 4) facilitates annealing of the nascent DNA with acceptor template. It would have been prima facie obvious to apply Allen et al's nucleocapsid protein to Legerski's US 6, 406, 891 B1 method for the synthesis of full length cDNAs utilizing highly processive RNA-dependent DNA polymerases in order to enhance processivity by over two orders of magnitude (col. 1, lines 50-65) because nucleocapsid protein can 1) increase the processivity of DNA synthesis by reducing RT pausing regions of stable secondary structures in the template RNA, 2) contribute to the synthesis of full-length viral cDNA, 3) increase the efficiency with which RT was able to reverse transcribe, 4) facilitate the annealing of the nascent DNA with acceptor template.

8. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hogrefe (US 6, 183, 997 B1 February 6, 2001).

Hogrefe (US 6, 183, 997 B1) teaches a method of selecting an agent which is capable of increasing the processivity of a DNA-dependent polymerase comprising an incubation of a candidate polymerase with a polymerization mixture and comparing the PCR product yields (col. 11, lines 1-11). Hogrefe also teaches nucleic acid replication reactions by providing length yields.

One of ordinary skill at the time the invention was made would have been motivated to modify Hogrefe (US 6, 183, 997 B1) method of selecting an agent which is capable of increasing the processivity of a DNA-dependent polymerase to include the length of the PCR product yield. It would have been prima facie obvious to modify Hogrefe (US 6, 183, 997 B1) method of selecting an agent which is capable of increasing the processivity of a DNA-dependent polymerase to include the length of the PCR product yield.

CONCLUSION

9. Claims **1-9 and 12-21** are rejected to for the reasons set forth above.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shar Hashemi whose telephone number is (703) 305-4840. The examiner can normally be reached Monday-Friday from 8:00AM – 5:00PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

The fax number for this examiner is (703) 746-9038. Before faxing any papers, please inform the examiner to avoid lost papers. Please note the faxing of papers must conform with

the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989). Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist, Tracey Johnson, whose telephone number is (703) 305-2982.

Examiner Hashemi

Ethan Whisenant
Primary Examiner

ETHAN WHISENANT
PRIMARY EXAMINER